K023256

APR 2 3 2003

510(K) SUMMARY
As Required By 21 CFR 807.92

Submitted by:

Janet Connolly, RAC
Sr. Regulatory Affairs Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730-6230

Device Name: Precision Xtra / MediSense Optium / Precision Easy / MediSense Optium Easy Blood Glucose Test Strip with True Measure Technology

Common Name: Self-Monitoring Blood Glucose System

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Predicate Device: Precision Xtra ® Blood Glucose Testing System, K010553

Description: The test strip is for blood glucose testing utilizes amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in whole blood and control solutions.

Intended Use: The test strip is intended for outside-the-body (*in-vitro* diagnostic) use. The system is indicated for the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger, forearm, upper arm or base of thumb), or by health care professionals. The test strip is to be used for monitoring blood glucose concentrations in persons with diabetes and other conditions.

Comparison to Predicate Device: The test strip has equivalent technological characteristics as the Precision Xtra Blood Glucose Test Strip (K010553). The test strip has the same intended use as the original test strip with the addition of forearm, upper arm and base of thumb.

Performance Studies: The performance of the test strip was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that lay users can obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurements, which include the predicate device listed above. The performance studies also demonstrate that testing blood glucose concentrations, during a steady state, are substantially equivalent

between the fingertip and alternative sites (i.e. forearm, upper arm or base of thumb).

Conclusion: Results of laboratory and clinical testing demonstrate that the performance of the test strip, when used according to the intended use stated above, is acceptable and comparable to the performance of the previously mentioned predicate device for blood glucose testing. In addition, results of clinical performance testing demonstrate that trained operators and lay users obtain equivalent whole blood glucose results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 3 2003

Ms. Janet Connolly, RAC
Senior Regulatory Submissions Specialist
Abbott Laboratories
MediSense Products
4A Crosby Drive
Bedford, MA 01730

Re: k023256
Trade/Device Name: Preision® Xtra® /MediSense® Optium™ Blood Glucose Test Strip with True Measure Technology
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: January 23, 2003
Received: January 24, 2003

Dear Ms. Connolly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K023256

Device Name: Precision® Xtra® / MediSense® Optium™ Blood Glucose Test Strip with True Measure Technology

Precision® Easy / MediSense® Optium™ Easy Blood Glucose Test Strip with True Measure Technology

Indications For Use:

The Precision Xtra / MediSense Optium / Precision Easy / MediSense Optium Easy Blood Glucose Test Strip is intended for outside-the-body (*in-vitro* diagnostic) use. The system is indicated for the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger, forearm, upper arm or base of thumb), or by health care professionals. The test strip is to be used for monitoring blood glucose concentrations in persons with diabetes and other conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use ✓
(Per 21 CFR 801.108)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023256